

Requested Patent: WO9908744A1

Title: A DISTAL PROTECTION/WASH-OUT METHOD FOR TREATING VESSELS ;

Abstracted Patent: WO9908744 ;

Publication Date: 1999-02-25 ;

Inventor(s): SHAKNOVICH ALEXANDER (US) ;

Applicant(s): SHAKNOVICH ALEXANDER (US) ;

Application Number: WO1998US16916 19980814 ;

Priority Number(s): US19970055834P 19970815 ;

IPC Classification: A61M29/00 ; A61M31/00 ;

Equivalents: AU8907498

**ABSTRACT:**

The present invention provides for a method, and apparatus for treating a vessel occluded by an obstructive lesion which avoids the clinical consequences associated with lesion disruption by creating a temporary obstruction (9) distal to the treatment site, thereby protecting vessels, and tissues which lie downstream; and washing out debris, and soluble factors (12) by introducing a wash solution (15) into the treatment site, then removing the wash solution at a location proximal to the treatment site thereby protecting upstream vessels, and tissues.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61M 29/00, 31/00		A1	(11) International Publication Number: <b>WO 99/08744</b>
			(43) International Publication Date: 25 February 1999 (25.02.99)
(21) International Application Number: PCT/US98/16916			(81) Designated States: AU, CA, IL, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 14 August 1998 (14.08.98)			
(30) Priority Data: 60/055,834 15 August 1997 (15.08.97) US			
(71)(72) Applicant and Inventor: SHAKNOVICH, Alexander [US/US]; Apartment 7F, 1349 Lexington Avenue, New York, NY 10128 (US).			
(74) Agents: TENSER, Arthur, S. et al.; Baker & Botts, LLP, 30 Rockefeller Plaza, New York, NY 10112-0228 (US).			

**Published**

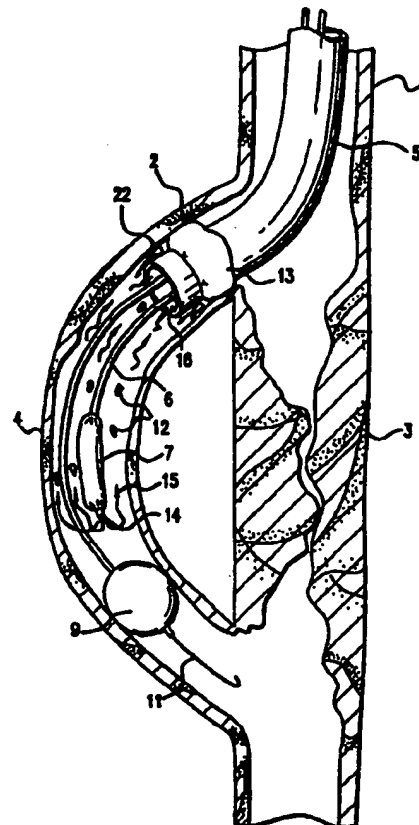
*With international search report.*

*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: A DISTAL PROTECTION/WASH-OUT METHOD FOR TREATING VESSELS

(57) Abstract

The present invention provides for a method, and apparatus for treating a vessel occluded by an obstructive lesion which avoids the clinical consequences associated with lesion disruption by creating a temporary obstruction (9) distal to the treatment site, thereby protecting vessels, and tissues which lie downstream; and washing out debris, and soluble factors (12) by introducing a wash solution (15) into the treatment site, then removing the wash solution at a location proximal to the treatment site thereby protecting upstream vessels, and tissues.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## A DISTAL PROTECTION/WASH-OUT METHOD FOR TREATING VESSELS

### 1. INTRODUCTION

The present invention relates to a method and apparatus for treating an  
5 occluded vessel which permits aggressive treatment but protects against adverse  
clinical events by creating a temporary occlusion distal to the treatment site and by  
washing out the treatment site and proximal vessel to remove undesirable debris and  
soluble factors.

### 2. BACKGROUND OF THE INVENTION

Over the past two decades, the field of interventional cardiology has  
witnessed a number of paradigm shifts in the treatment of occluded ("stenotic")  
coronary arteries. The earliest approach, still used for particular coronary applications,  
is by-pass surgery, which constructs a vascular detour around the occlusion. Often the  
15 detour is created by grafting a portion of a large vein of the subject, for example, the  
saphenous vein, to the diseased coronary artery to bypass the occlusion.  
Unfortunately, in a substantial number of patients, the graft itself becomes affected by  
atherosclerotic disease, and is partially (eventually completely, without treatment)  
occluded.

20 An approach less invasive than by-pass surgery, which does not require  
thoracotomy and which is appropriate in certain patients, is percutaneous transluminal  
coronary angioplasty ("PTCA"), which introduces a catheter carrying a deflated  
balloon into a large artery in the leg or arm of a patient, threads the catheter through  
the aorta and into an occluded coronary artery, and then inflates the balloon to force  
25 open the obstruction. PTCA may be particularly appropriate for treating an  
obstructive lesion in an occluded by-pass graft.

However, PTCA is not without risk. Sometimes an obstructive lesion  
must be debulked to permit introduction of the balloon, and the debulking procedure  
may release fragments of the lesion into the circulation. Such fragments can  
30 potentially result in morbidity or mortality, as they may travel either downstream, to  
cause an occlusion and tissue infarction, or upstream (into the ascending aorta) to

produce an embolic stroke. Similar effects can result from soluble factors, which may promote thrombus formation, spasm, endothelial cell proliferation, or inflammation, released from normal or diseased tissues during a treatment procedure. The likelihood of such undesirable clinical sequelae may be lessened by the aggressive use of  
5 anticoagulants and/or vasodilators, which carry their own risks, including, but not limited to, hemorrhage and cerebral infarction. Further, in 30-50% of patients treated with PTCA, the subsequent healing process in the treated coronary artery is associated with sufficient recoil, scarring and/or proliferation of smooth muscle cells to cause re-occlusion of the artery (called "restenosis").

10               There is therefore a need for a method for avoiding the consequences of fragmentation of obstructive lesions which would nevertheless permit the aggressive treatment of such lesions so as to minimize the likelihood of disease recurrence. In particular, such a method would be useful for treating obstructed saphenous vein by-pass grafts.

15

### 3. SUMMARY OF THE INVENTION

The present invention provides for a method and apparatus for treating a vessel occluded by an obstructive lesion which avoids the clinical consequences associated with lesion disruption by (i) creating a temporary obstruction distal to the  
20 treatment site, thereby protecting vessels and tissues which lie downstream (the "distal protection" step); and (ii) washing out debris and chemicals by (a) introducing a wash solution into the treatment site and then (b) removing the wash solution at a location proximal to the treatment site (the "wash-out" step), thereby protecting upstream vessels and tissues. The method of the invention may be used in conjunction  
25 with any technique which reduces the extent by which an obstructive lesion occludes a vessel, including, but not limited to, methods which dilate the vessel, debulk the lesion (mechanically, ultrasonically, enzymatically, etc.), and/or place a stent within the vessel.

The method of the invention provides a number of advantages. It may  
30 be used in the treatment of vessels having occluded portions of a wide range of length and severity, regardless of the presence of thrombus or caliber and quantity of distal

branches of the target vessel. It may decrease the need for aggressive anticoagulation, use of platelet aggregation inhibitors, thrombolytic agents or vasodilators. Further, in specific non-limiting embodiments, the method of the invention may be practiced using conventional equipment routinely used by interventional cardiologists.

5           The present invention also provides for a guiding catheter having an expandible portion at its distal end which prevents backflow of wash fluid during the wash-out step.

          The drawings, FIGURES 1-9, depict a non-limiting embodiment of the present invention, where the distal protection/wash-out method, using a guiding  
10 catheter having a distal expandible segment, is used in the dilatation treatment and scaffolding of a saphenous vein graft ("SVG"; 2) by-pass in a coronary artery (1) having an occlusion (3). The SVG (2) has an occlusive obstructive lesion (4), having friable portions (12).

          In FIGURE 1, a guiding catheter (5) having an expandible segment  
15 (13) in unexpanded configuration, and containing a first catheter (8) having a distal occluder balloon (9) over a first guide wire (11) and a second catheter (6) having a distal treatment balloon (7) over a second guide wire (10), is positioned in the SVG (2). Both guide wires (10 and 11) traverse the diseased portion (20) of the SVG (which, in this case, coincides with the treatment site).

20           In FIGURE 2, the first catheter (8) is advanced over the guide wire (11) such that its uninflated occluder balloon (9) traverses the obstructive lesion (4), and lies in an undiseased portion (21) of the SVG (2).

          In FIGURE 3, the occluder balloon (9) is inflated, thereby creating a temporary obstruction to blood flow in the SVG (2; distal protection) and pressing  
25 the second guidewire (10) between the inflated occluder balloon (9) and the vessel wall. Also, the second catheter (6) is advanced over the guide wire (10) such that its uninflated treatment balloon (7) is placed within the obstructive lesion (4).

          FIGURE 4 depicts a first treatment step in which the treatment balloon (7) has been inflated, thereby compressing a proximal portion of the obstructive lesion  
30 (4), and detaching several friable fragments (12), which move toward the inflated occluder balloon (9) (soluble factors would also be released, but are not shown).

FIGURE 5 depicts a second treatment step in which the treatment balloon (7), after having been deflated, is repositioned and re-inflated in a more distal location so as to compress the obstructive lesion (4) in the remainder of the diseased segment (20) of the SVG (2), thereby liberating additional friable fragments (12), which have accumulated on the proximal side of the inflated occluder balloon (9).

FIGURE 6 depicts a wash-out step, in which the treatment balloon (7) has been deflated and its guide wire (10) withdrawn from the patient, and the treatment balloon is positioned just proximal to the inflated occluder balloon (9). Wash fluid (15; represented by arrows) is being infused through wire port of the treatment balloon catheter (6), and is carrying the detached friable fragments (12) (and any soluble factors) proximally. The expandible portion (13) of the guiding catheter (5) is inflated and blocks the passage of these fragments and soluble factors into the proximal circulation (represented by curved arrows;22). The exhausted wash fluid containing the debris from the procedure, including the detached friable fragments (12) and soluble factors, is aspirated out of the treatment site through the distal tip of the guiding catheter (16).

Subsequently to the step shown in FIGURE 6, the occluder balloon and the expandible portion of the guiding catheter are deflated, the treatment balloon and its catheter, and the occluder balloon and its catheter are withdrawn from the patient, leaving in place the guiding catheter and the first guide wire.

FIGURE 7 shows a scaffolding step, where a catheter having a distal balloon (17) carrying an expandible stent (18) is passed over the first guide wire (11) into the treatment site (over what had been the obstructive lesion, 4). In FIGURE 8, the balloon is expanded, thereby deploying the stent (18). FIGURE 9 depicts the scaffolded treatment site (19).

#### **4. BRIEF DESCRIPTION OF THE FIGURES**

FIGURE 1 depicts a guiding catheter containing a treatment balloon catheter and an occluder balloon catheter in an occluded saphenous vein graft (SVG).

FIGURE 2 depicts positioning of the occluder balloon at a location  
5 distal to the treatment site.

FIGURE 3 depicts a distal protection step in which the occluder balloon is inflated, creating a temporary obstruction, and the treatment balloon is positioned within the obstructive lesion.

FIGURE 4 depicts a treatment step in which the treatment balloon is  
10 inflated to decrease the extent of occlusion, detaching friable fragments of the lesion which pass distally.

FIGURE 5 depicts a second treatment step in which a more distal portion of the diseased segment is opened by inflation of the treatment balloon.

FIGURE 6 depicts a wash-out step, in which wash fluid is perfused  
15 through the more distally located treatment balloon catheter (the balloon having been deflated), and passes retrogradely, where the debris-containing wash fluid is aspirated through the distal tip of the guiding catheter and out of the patient. The guiding catheter has an expanded distal portion which blocks the wash fluid and debris from entering the proximal circulation.

FIGURE 7 shows a scaffolding step, where a balloon catheter carrying  
20 a stent is positioned within the treatment site.

FIGURE 8 shows a second scaffolding step where the stent is deployed.

FIGURE 9 shows the scaffolded SVG following treatment.



## 5. DETAILED DESCRIPTION OF THE INVENTION

The present invention provides for a method of treating a vessel occluded by an obstructive lesion at a treatment site comprising (i) creating a temporary obstruction distal to the treatment site; (ii) decreasing the extent that the obstructive lesion occludes the vessel; and (iii) washing out debris and soluble factors by (a) introducing a wash solution into the treatment site and then (b) removing the wash solution carrying debris and soluble factors at a location proximal to the treatment site.

The terms "proximal" and "distal", as used herein, refer to a directionality established by the actual or intended introduction of the elements disclosed into a subject, wherein the direction moving away or further from the point of introduction in the subject is "distal" and the direction moving toward or nearer the point of introduction is "proximal". For example, where a catheter is inserted into the femoral artery of a subject via an access site in the groin, but one end of the catheter is held by an operator, and then the inserted tip of the catheter is passed through the femoral artery and into the aorta, the inserted tip is the distal tip of the catheter and the operator is holding the proximal end of the catheter, and the inserted tip is being moved distally. When the catheter is withdrawn from the patient, the distal tip is moved proximally.

A vessel which may appropriately be treated (hereafter referred to as a "target vessel") desirably lacks major proximal side branches which would provide alternate routes for dispersal of fragments or flow of wash fluid. Thus, the method of the invention would operate at a site essentially having boundaries defined by the target vessel walls, the distally located temporary obstruction, and a more proximally located catheter through which exhausted wash fluid is withdrawn. Small branch vessels may arise from the target vessel provided that passage of lesion fragments or wash fluid into said vessel(s) would not be associated with a substantial likelihood of clinically adverse consequences. A preferred target vessel is a saphenous vein by-pass graft bridging an occluded portion of a coronary artery, although any vessel or conduit in the body may serve as a target vessel provided that it meets the abovementioned structural constraints.

Obstructive lesions according to the invention may be, for example but not by way of limitation, atherosclerotic, fibrotic, malignant or infectious in character. The obstruction may lie within the target vessel and/or in or around the walls of the vessel.

5           The treatment site is defined as that location in which a procedure which may liberate lesion fragments or soluble factors is performed. It typically, but not always, would comprise all or a portion of the obstructive lesion associated with vessel occlusion.

          A vessel is defined as being "occluded" herein if the lumen of the  
10   vessel is decreased, by an obstructive lesion, relative to its natural diameter absent the obstructive process. Thus, occlusion need not, and preferably, is not, complete, so as to permit passage of the temporary obstructive element to a location distal to the lesion. However, in less preferred embodiments of the invention and where clinically warranted, the temporary obstructive element may be placed within or even proximal  
15   to the lesion, provided that it lies distal to the treatment site.

          The temporary obstruction may be created by a temporary obstructive element (hereafter, the "occluder") which may exist in a passive or an activated configuration. In its passive configuration, the occluder may be introduced into the target vessel and into or past the occluded region of the vessel. When activated,  
20   however, the occluder expands to a diameter which substantially occludes the passage of fluid past it, but it must be able to be returned to a passive configuration so as to permit withdrawal from the patient. The occluder preferably is comprised at the distal end of a catheter. In preferred nonlimiting embodiments of the invention, the occluder is a balloon, but any reversible means of expansion may be used to achieve the  
25   activated configuration, including a nitinol wire, or mechanical means. The occluder may incorporate means for passive or active perfusion of the distal vessel, so as to avoid infarction, such as a conduit which would allow blood or other perfusate to pass from the area proximal to the expanded occluder to the area distal to it, such as small  
30   holes in the shaft of a catheter attached to the occluder proximal to and distal to the occluder element, which preferably are of a size or material which would prevent or inhibit passage of debris or soluble factors past the expanded occluder into the distal

vessel.

In a specific nonlimiting embodiment of the invention, the occluder may be a compliant PTCA balloon. Over-the-wire or monorail, but not perfusion, balloons may be used as occluders. The size of the occluder balloon is chosen so that  
5 complete occlusion may be effected distal to the treatment site at very low pressures, optimally less than two atmospheres, in order to minimize the risk of injury to the region of the vessel where temporary obstruction is effected. Preferably, the occluder is placed sufficiently distally to permit treatment of the entire length of the obstructive lesion, such that the occluder, when activated (*i.e.*, expanded), lies within a relatively  
10 disease free segment of the target vessel distal to the obstructive lesion. Contrast agent may be injected into the target vessel in order to confirm that obstruction with the activated occluder is complete. A larger diameter occluder may be needed if the initial occluder (for example a balloon inflated to low pressure) does not prevent contrast agent from passing distal to the activated occluder.

15 The extent that the obstructive lesion occludes the target vessel may be decreased by any means known in the art, including, but not limited to, dilatation using a balloon or equivalent instrument, placement of a stent, or debulking. Debulking may be performed mechanically, ultrasonically, chemically or enzymatically; suitable agents which may be used include but are not limited to  
20 heparin, hirudin, hirudin-related peptides including Hirulog, anti-platelet agents including Reopro, and thrombolytics such as tissue plasminogen activator, streptokinase, urokinase, and thromboplastin. The step of decreasing the extent of occlusion is referred to herein as the treatment step (and was referred to in priority application no. 60/055,834 as the "pre-treatment step").

25 Preferably stent placement is performed after an obstructive lesion has been treated and after the wash-out procedure has been completed, as a separate "scaffolding step". Stents which may be used according to the invention include but are not limited to Palmaz-Schatz, Gianturco-Roubin, Cook, AVE, Strecker, Wiktor, Wallsten and Cordis stents. Stents which are expandible by ancillary means or self-  
30 expanding stents may be used. To reduce the risk of distal embolization during scaffolding, balloon-expandible stents may be delivered on deployment balloons of

the same diameter (when expanded) as, or smaller diameter than, the treatment balloon. Similarly, self-expanding stents desirably have a diameter, in their expanded configuration, which does not exceed that of the treatment balloon used to dilate the target vessel at the treatment site. When required, post-deployment expansion of stents may be performed with balloon(s) preferably of the same diameter as, or of smaller diameter than, the treatment balloon at a maximal pressure below that used during pre-treatment. In a specific non-limiting embodiment of the invention, the treatment balloon may be used as the deployment balloon for a biliary Palmz stent.

The occluder and any elements used in the treatment step are brought into proximity to the lesion by a guiding catheter, which may be of a length which reaches and may optionally enter the ostium of the target vessel, of an inner diameter which may accommodate simultaneously or sequentially the occluder and treatment elements, and of an outer diameter to permit safe passage to the desired location. For example, and not by way of limitation, 9F and 10F guiding catheters may be used. Side holes in the guiding catheter are desirably avoided to facilitate effective removal of exhausted wash fluid. In nonlimiting embodiments, where the guiding catheter is to be used in procedures involving the coronary arteries or saphenous vein grafts, the inner diameter may be in the range of from 0.8 to 1.6 millimeters, and preferably from 0.9 to 1.3 millimeters. A guiding catheter having a modified distal end which may adopt an activated expanded configuration which prevents the proximal passage of exhausted wash fluid (backflow), as illustrated in FIGURE 6, may desirably be used. For example, such an expanded configuration may be achieved by a balloon or other mechanical element. In nonlimiting examples of the invention, the expandible element may be comprised in the distal 50 millimeters of the guiding catheter, and may itself have a length of, preferably, 5 to 35 millimeters, and more preferably from 9 to 30 millimeters, and the diameter of the expandible element, in expanded configuration, for coronary artery and saphenous vein graft applications, may range from 2.0 to 6.0 millimeters and preferably from 3.0 to 5.0 millimeters, inclusive.

The occluder and the treatment elements are preferably, but not necessarily, introduced into the target vessels and through the guiding catheter over separate guide wires. In two guide wire embodiments of the invention, one guide

wire, used to position treatment elements, remains trapped between the vessel wall and the activated occluder (for example, during treatment), and is then withdrawn to a location proximal to the activated occluder prior to the wash-out step. In a preferred specific non-limiting embodiment of the invention, two Choice PT™ wires are used to facilitate retraction of the wire trapped by the occluder. However, if the means of treatment could use the shaft of a catheter attached to the occluder as a guide, (e.g. if the occluder is attached to a hollow wire, a "balloon on the wire"), only a single guide wire would be necessary.

The wash solution may be any physiologically compatible fluid, including but not limited to normal saline, Ringer's solution, etc., and may comprise one or more other compounds, including, but not limited to, contrast agent(s), anticoagulant agent(s) and/or enzyme(s), antibiotic(s), vasoactive substance(s), and so forth. Once it has been used to wash the treatment site, it is referred to as "exhausted wash fluid".

In preferred embodiments of the invention, the object of the treatment step is not only to decrease the extent of vessel occlusion, but also to dislodge, express, and liberate from the vessel walls any friable and/or non-solid material which may cause distal embolization or no reflow. Accordingly, treatment is preferably vigorous and uses aggressive measures. As a nonlimiting example, where treatment is dilatation by expansion of a balloon, a balloon at the treatment site may be inflated up and down the treatment site to relatively high pressure, for example, 12-16 atmospheres; where a subsequent scaffolding step is planned, these treatment step inflation pressures are desirably equal to the pressure the operator intends to use for high-pressure post-deployment stent dilatation. Multiple overlapping inflations may be necessary. The duration of each inflation is desirably limited to the time required to achieve full balloon expansion in order to minimize overall ischemic time.

Further, treatment should involve not only the most severely occluded portion of the target vessel, but any contiguous or non-contiguous less severely affected portion as well. Treatments, including distal protection and wash-out steps, may be performed sequentially in the same target vessel.

It should be noted that although the instant invention may decrease the

risk of adverse clinical events, morbidity or mortality could nonetheless potentially result from the obligatory ischemic time during treatment and wash-out steps, from coronary or non-coronary embolization, or from endothelial trauma incurred during the procedure.

- 5                   A non-limiting specific example of the practice of the instant invention is set forth below.

## 6. EXAMPLE

10                   The method of the invention may be used in the treatment of a subject having a saphenous vein graft (SVG), which had been placed in a by-pass procedure to treat an occluded coronary artery, but which is now itself partially occluded. The following procedure may be used to dilate the occluded portion of the SFG (the target vessel), using the distal protection/wash-out method of the invention, and then to place a stent in the SVG to maintain its patency.

- 15                   Equipment used in the procedure may include (i) a 9F guiding catheter; (ii) a first guide wire, over which may be passed (iii) a first balloon catheter, wherein the balloon will serve as the occluder (and is hereafter referred to as the "occluder balloon" or "occluder"), attached to a means of inflating the occluder balloon; (iv) a second guide wire, over which may be passed and (v) a second balloon catheter, 20 wherein the balloon will be used in a treatment step (and is referred to hereafter as the "treatment balloon") to dilate the occluded portion of the SVG, attached to a means of inflating the treatment balloon. The proximal end of the second balloon catheter may be attached to a Y-adaptor, one arm of which may be attached to a three-way stopcock which may be connected to (i) a small (e.g., 3-5cc) saline-filled syringe and (ii) a 25 larger (10-20 cc) syringe containing wash fluid. Further, the guiding catheter may comprise, at its proximal end, an attachment site for a means for removing exhausted wash fluid, such as an empty 20-30 cc syringe (henceforth, the "aspiration syringe"). Another separate piece of equipment may be a stent mounted on the balloon (henceforth, the "deployment balloon") of a third balloon catheter, and a third guide 30 wire which may be used for introduction of the guiding catheter.

Using conventional techniques as are used in a PTCA or stent

placement procedure, the guiding catheter may be passed, over the third guide wire, into the femoral artery of the subject and passed through the aorta and into the SVG, to a position proximal to the occluded segment, and the third guide wire may then be withdrawn once the guiding catheter is in position. Then, the first and second guide  
5 wires may be passed through the guiding catheter to traverse the occluded SVG segment.

In subsequent steps, the first and second balloon catheters may be passed into and through the guiding catheter either simultaneously, as is shown in FIGURE 1, or sequentially (*e.g.*, first the first balloon catheter comprising the  
10 occluder, and then the second balloon catheter comprising the treatment balloon).

In the distal protection step, the catheter bearing the occluder balloon is advanced over the first guide wire so that the occluder balloon is in a position which is distal to the intended treatment site, which preferably constitutes all or most of the diseased segment of the SVG. The occluder balloon is then inflated at a pressure high  
15 enough to effect complete occlusion, but low enough to minimize or avoid injury to local vessel walls (which may be part of the SVG or the coronary artery to which the graft was anastomosed); this pressure is preferably less than 2 atmospheres. By inflating (activating) the occluder, the second guide wire becomes trapped between the expanded occluder and the vessel wall. Contrast injection into the SVG may be  
20 used to confirm that the vessel is completely occluded.

In the treatment step, the treatment balloon may be advanced over the second guide wire, and inflated and deflated so as to dilate the segment of the SVG occluded by disease. The inflations and deflations may be performed multiple times and at different positions along the diseased SVG (the entire area constituting the  
25 treatment site). Preferably, the inflations are at relatively high pressures, such as 12-16 atmospheres. During this step, friable fragments of the SVG wall and lesions associated with it may be broken free and pass distally, until they are stopped from progressing further by the activated occluder balloon.

After the treatment step is completed, the treatment balloon may be  
30 advanced distally over the second guide wire until it reaches the activated occluder. Then, the second guide wire may be pulled out of the treatment balloon (past the

activated occluder balloon) and its attached catheter. To avoid entraining air during the wire pull out, saline from the small syringe connected to the stopcock attached to the Y adapter may be flushed through the Y-adapter, which comprises an O-ring which is partially open. Once the second guide wire is completely out of the treatment  
5 balloon, the O-ring of the Y adapter may be tightened, and the stopcock may be turned off to the treatment balloon.

In the wash-out step, the treatment site is perfused as the operator flushes the wash fluid (via the 10-20 cc syringe attached to the stopcock attached to the Y adapter) through the wire port of the treatment balloon catheter and,  
10 simultaneously, the operator or an assistant aspirates exhausted wash fluid via the guiding catheter tip and into an aspiration syringe.

After the wash-out step is completed, the treatment balloon catheter is withdrawn first, followed by deflation and removal of the occluder balloon catheter, with the first guide wire remaining in place across the treatment site of the SVG.

15 In the scaffolding step, the catheter bearing, at its distal end, the deployment balloon may then be passed over the first guide wire, and the stent positioned and deployed into the treatment site. Preferably, the entire treatment site is scaffolded by the placement of one or more stent.



## I CLAIM:

1. A method of treating a vessel occluded by an obstructive lesion at a treatment site comprising (i) creating a temporary obstruction distal to the treatment site; (ii) decreasing the extent that the obstructive lesion occludes the vessel; and (iii) washing out debris and soluble factors by (a) introducing a wash solution into the treatment site and then (b) removing the wash solution at a location proximal to the treatment site.
2. The method of claim 1 in which the wash solution is introduced such that it flows through the vessel in a proximal direction.
3. The method of claim 1 in which the extent that the obstructive lesion occludes the vessel is decreased by dilating the vessel at the treatment site.
4. The method of claim 1 in which the extent that the obstructive lesion occludes the vessel is decreased by debulking the lesion.
5. The method of claim 1 in which the extent that the obstructive lesion occludes the vessel is decreased by placing a stent at the treatment site.
6. The method of any of claims 1-5 where the vessel is a bypass graft.
7. The method of any of claims 1-5 where the vessel is a coronary artery.
8. The method of any of claims 1-5 where the wash fluid is removed via the tip of a guiding catheter having, at its distal end, an expandible element which prevents backflow of wash fluid into the proximal circulation.
9. A guiding catheter having, at its distal end, an expandible element.

1/9

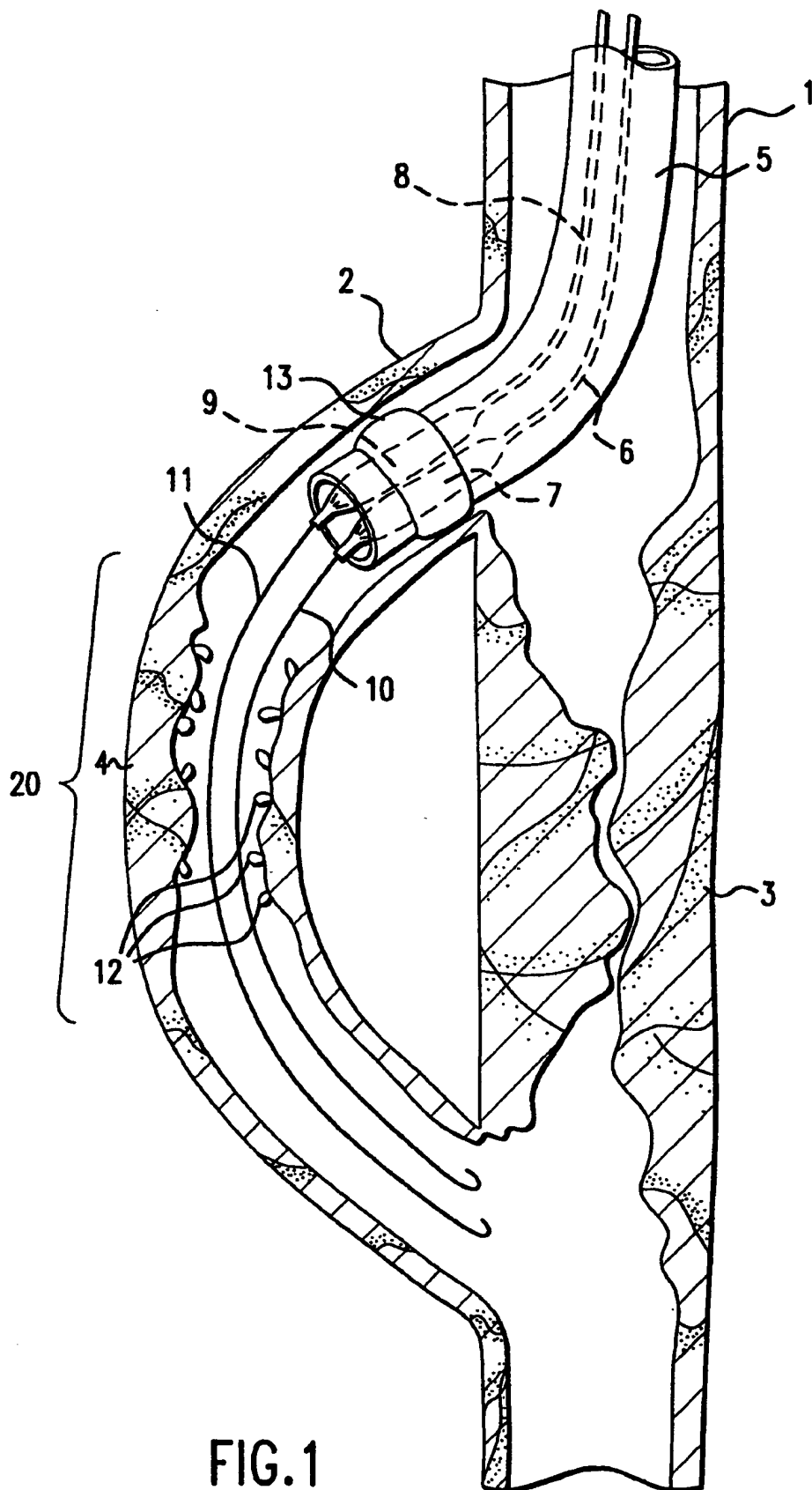


FIG. 1

2/9

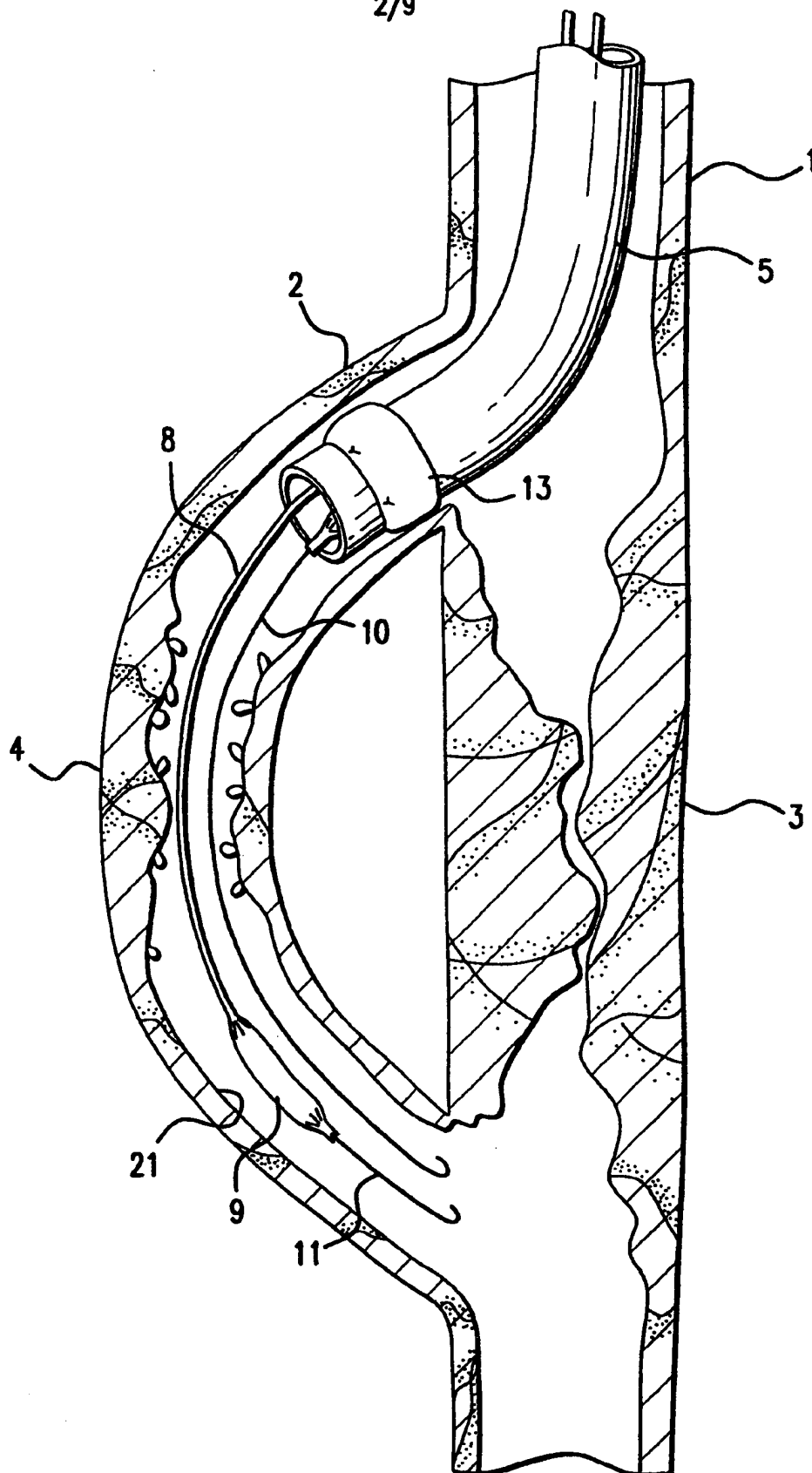


FIG.2

3/9

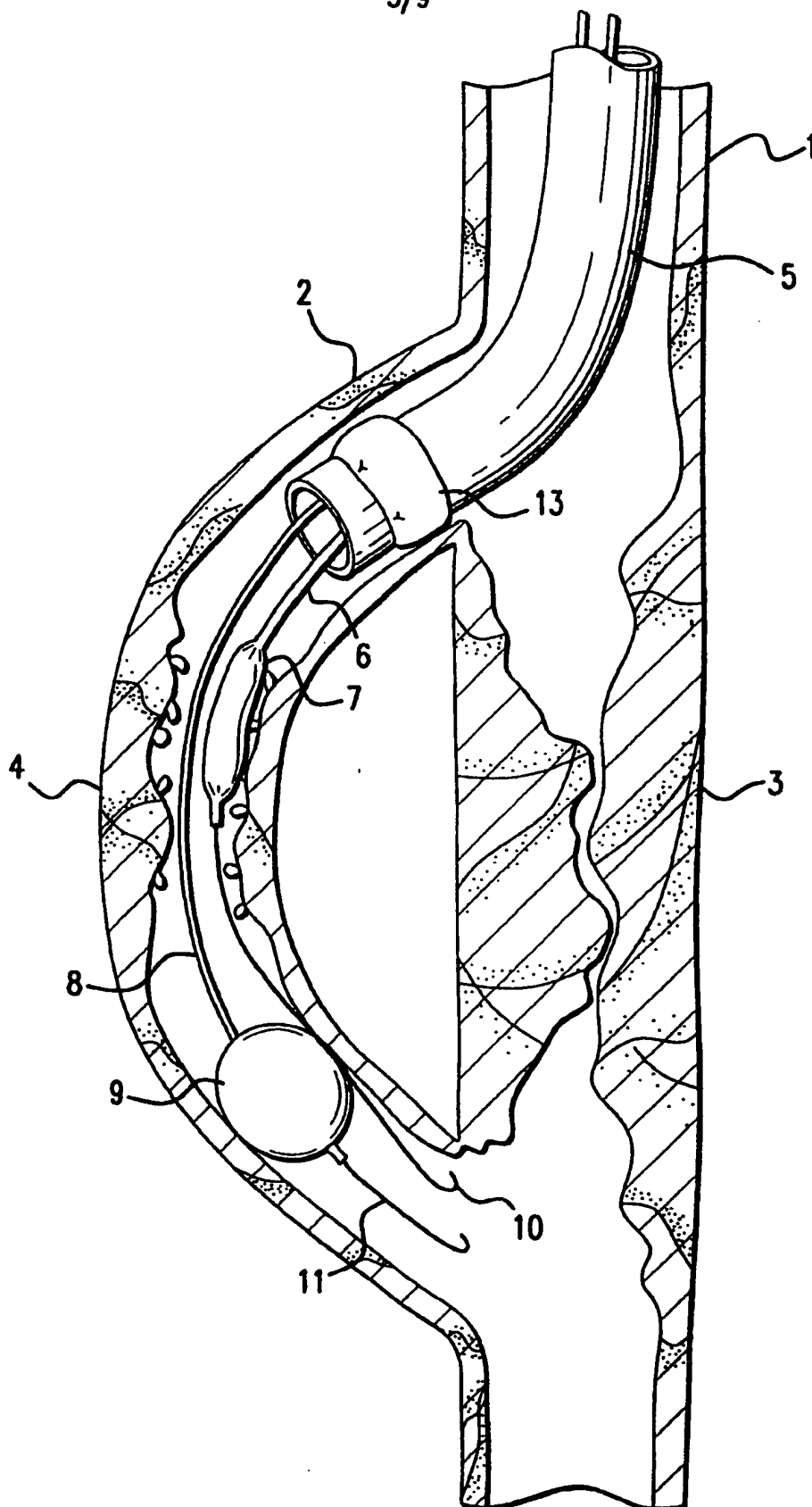


FIG.3

4/9

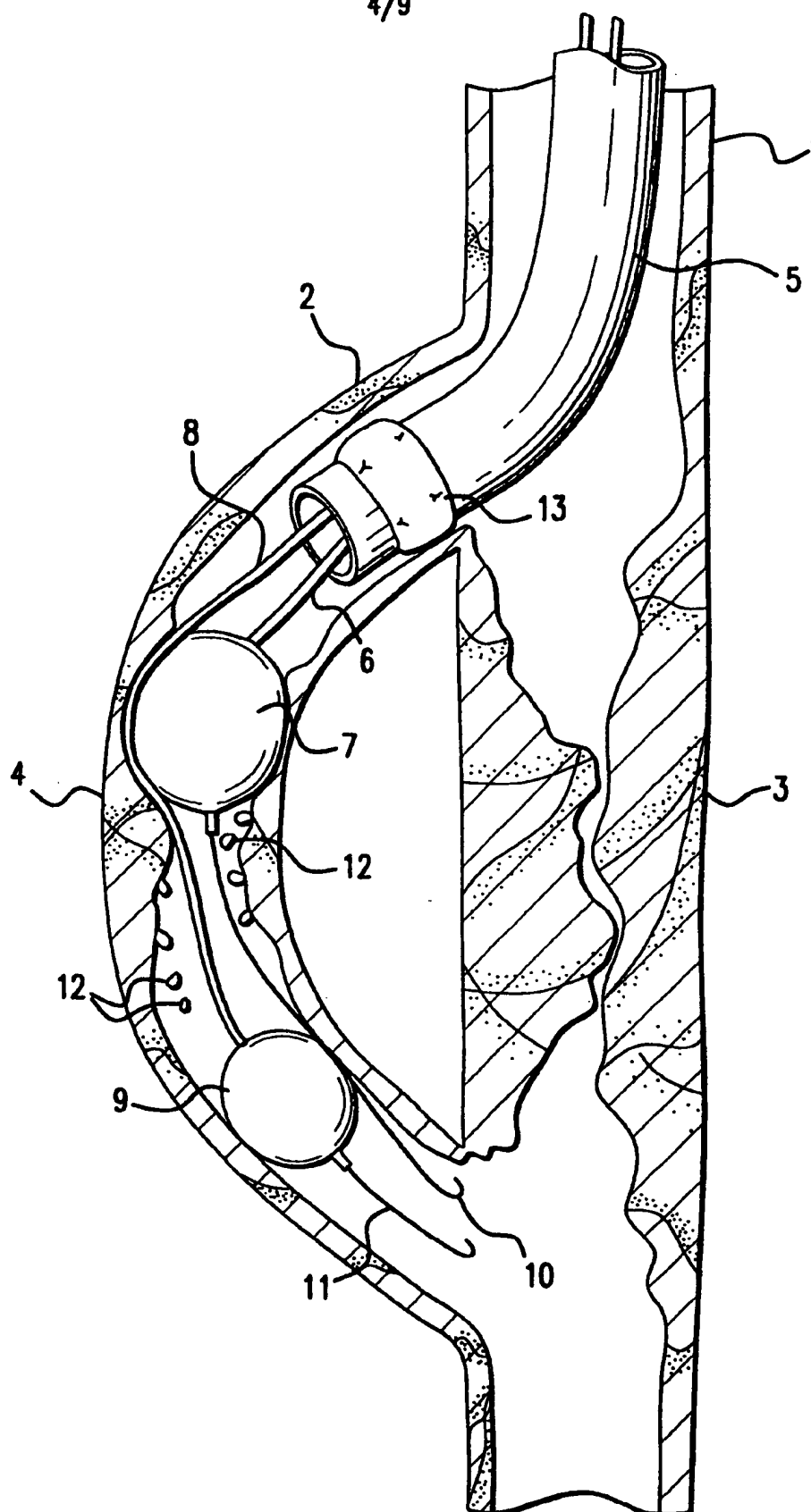


FIG. 4

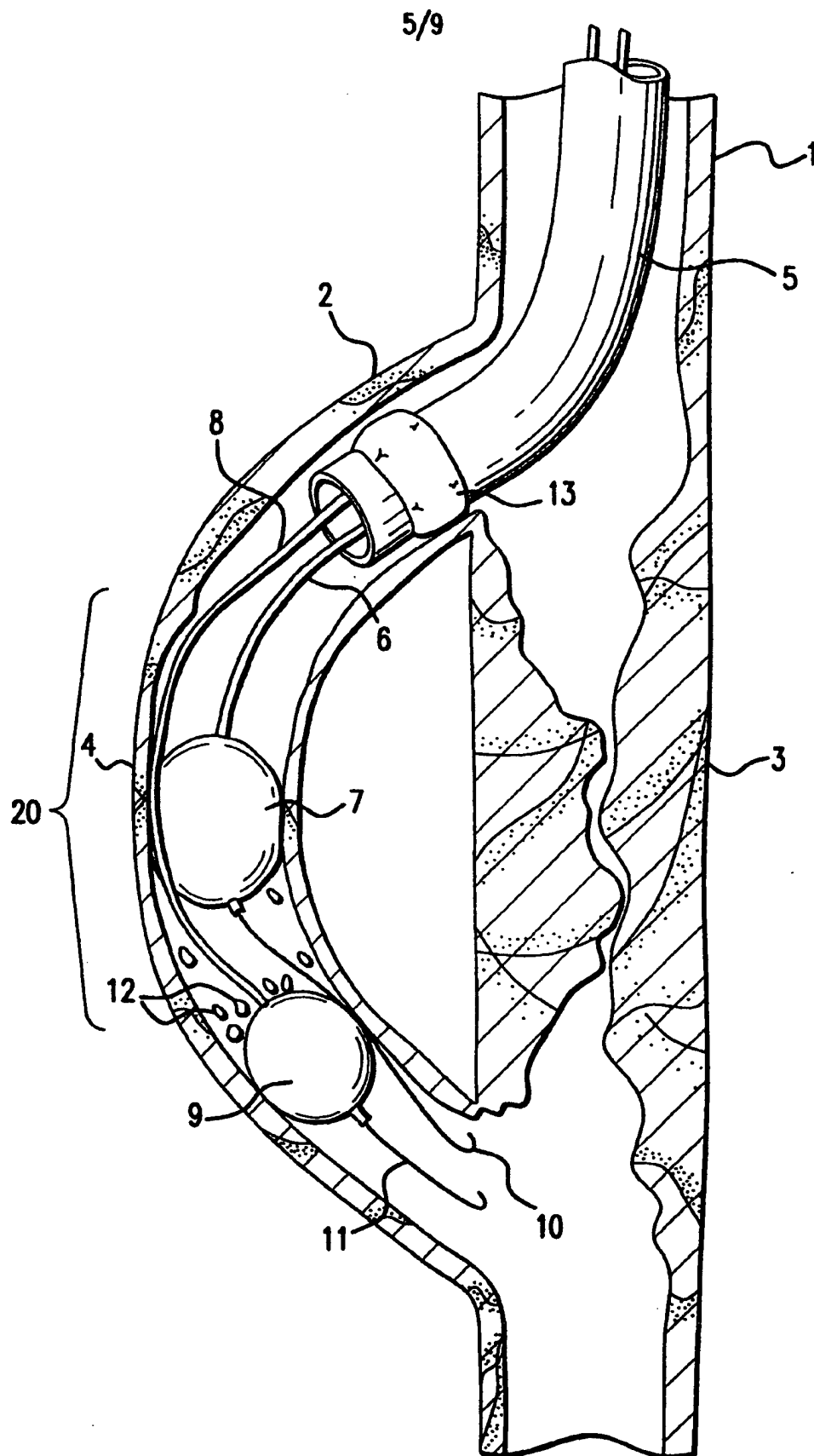


FIG.5

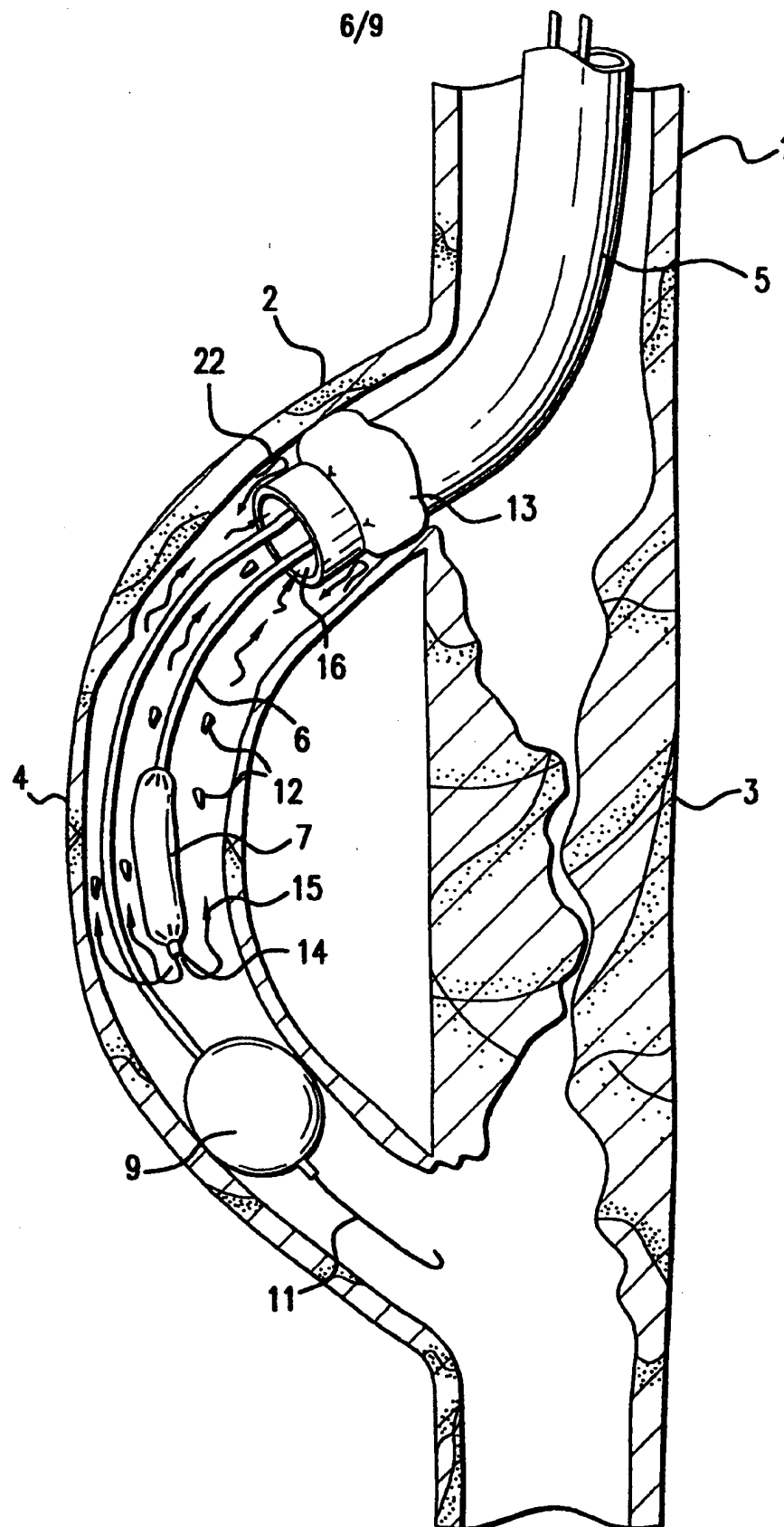


FIG. 6

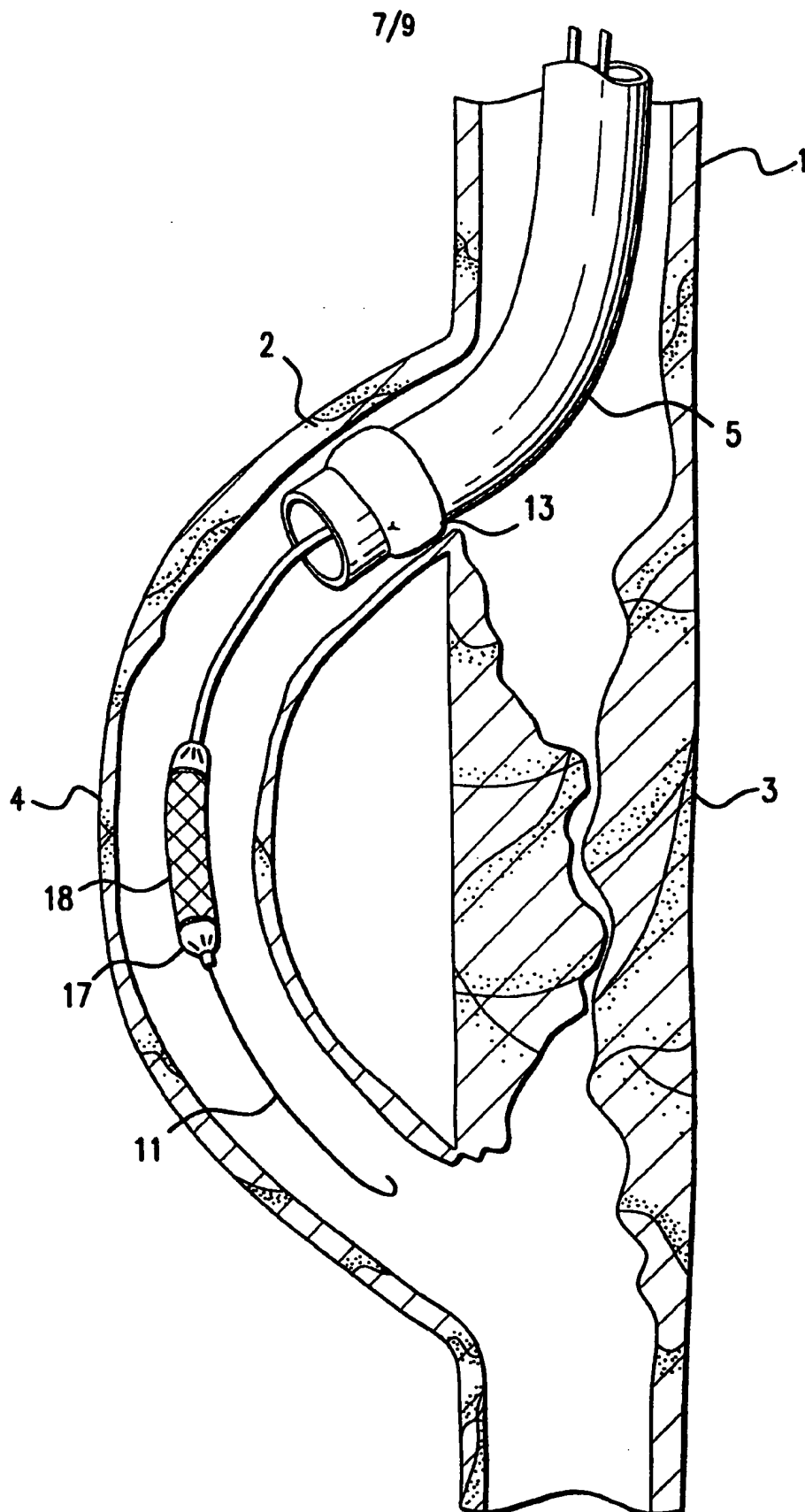


FIG. 7



8/9

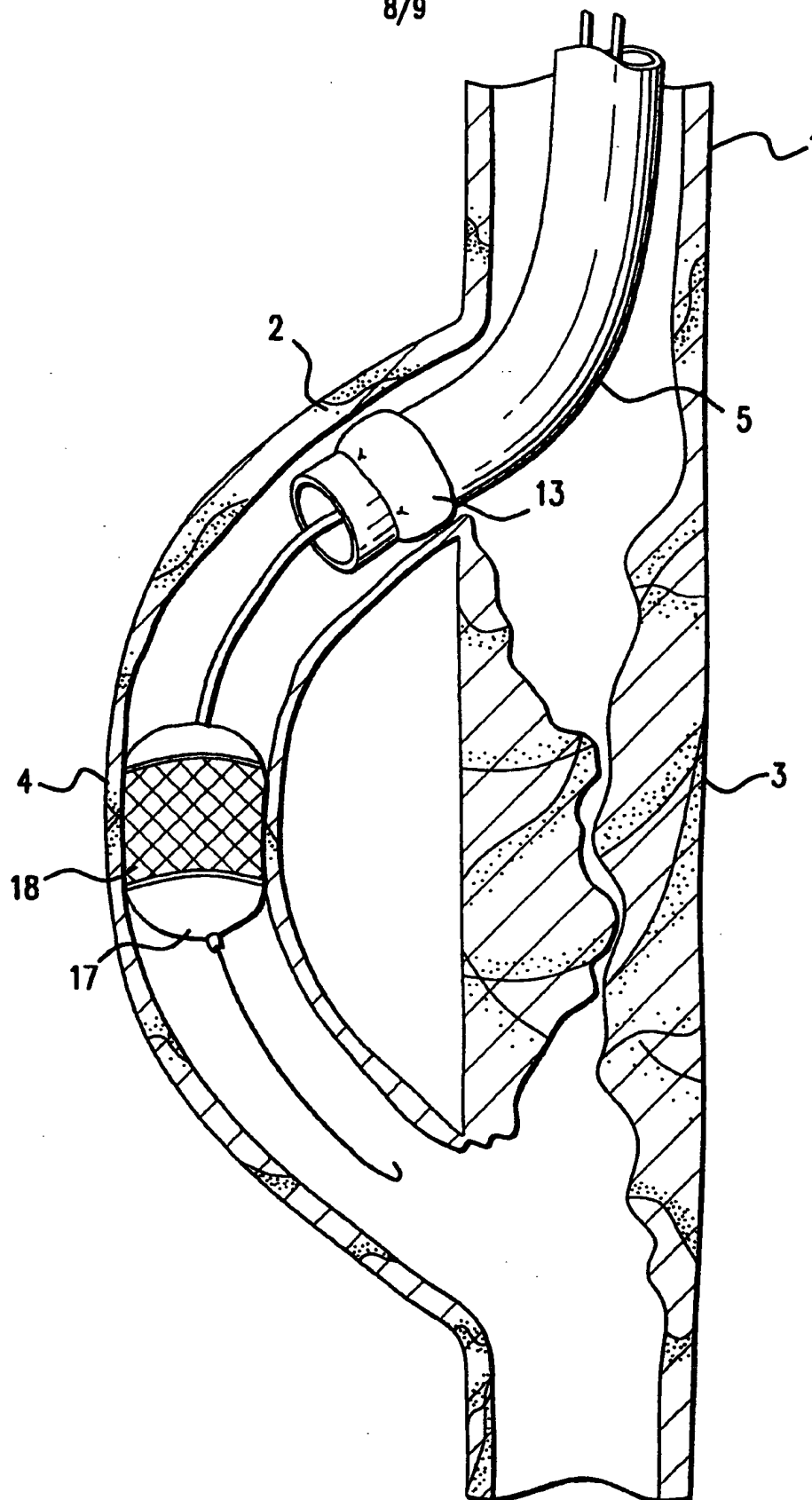


FIG. 8

9/9

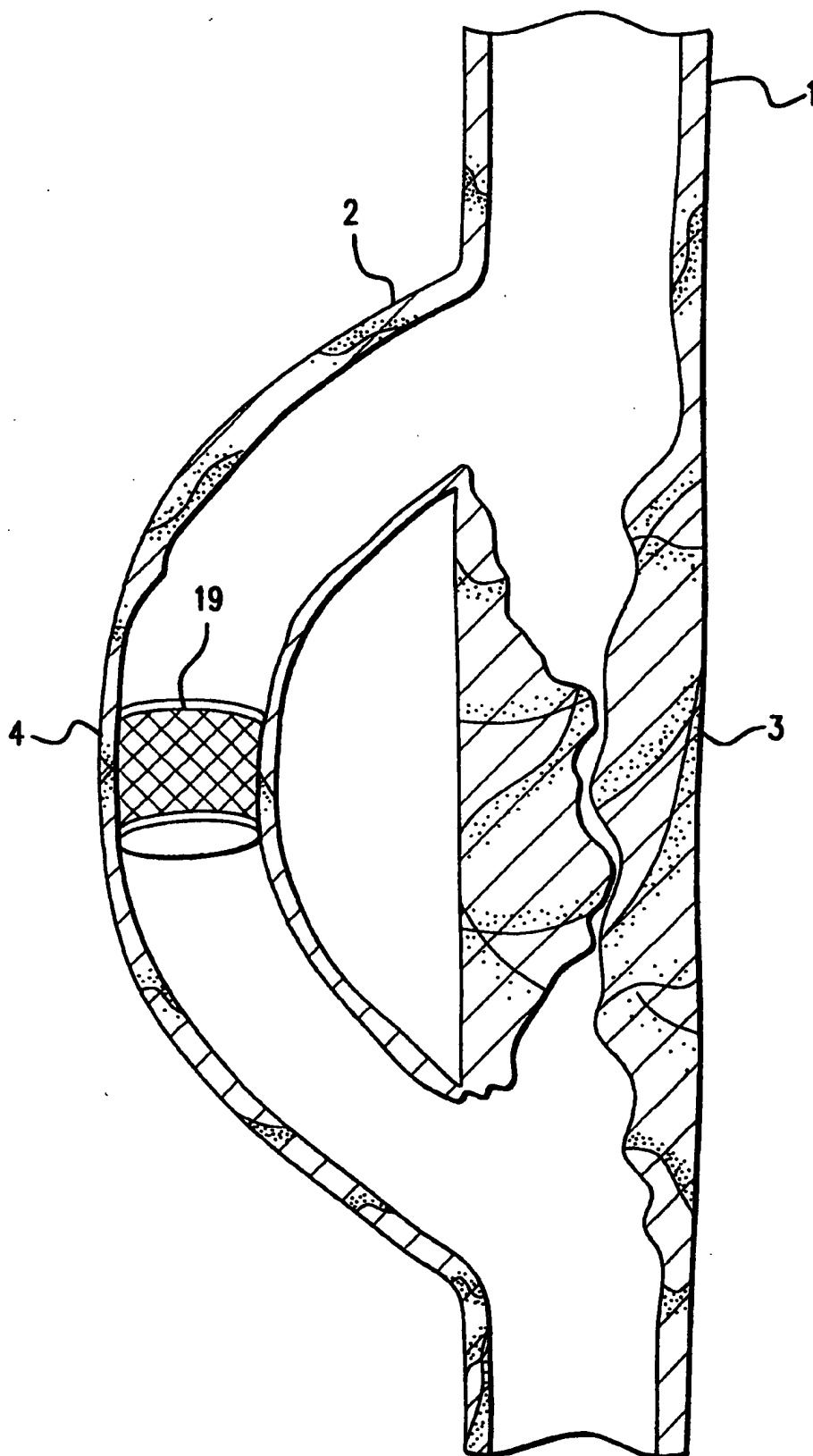


FIG. 9

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/16916

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00, 31/00

US CL :604/49, 96

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/22, 28, 49, 96

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

Search Terms: method, balloon, wash?, oculus?, block?, obstruct?, temporary

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,883,460A (ZANETTI) 28 November 1989, claims, figures, Abstract, and col 2 lines 53-67.	1-9
X	US 4,772,258 A (MARANGONI et al.) 20 September 1988, claims, figures, Abstract, and col 2 lines 18-27.	1-8
A	US 3,828,782 A (POLIN) 13 August 1974.	1, 2, 9
Y	US 5,320,617 A (LEACH) 14 June 1994, claims, Abstract, and figures.	1, 2, 5, 8, 9
Y	US 4,637,814 A (LEIBOFF) 20 January 1987, claims, figures, Abstract, and col. 21 lines 41-56.	1, 2, 5, 8, 9

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

04 NOVEMBER 1998

Date of mailing of the international search report

18 DEC 1998

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JENNIFER R. SADULA

Telephone No. (703) 308-2977

**INTERNATIONAL SEARCH REPORT****International application No.  
PCT/US98/16916****C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,443,478 A (PURDY) 22 August 1995, claims, figures, and Abstract.	1-7